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TITLE: Pressure Relief Behaviors and Weight-Shifting Activities to Prevent Pressure Ulcers in Persons with SCI

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14. ABSTRACT

Pressure ulcers (PU) are the most costly secondary complication following an SCI. In addition to the medical costs, the development of a pressure ulcer adversely impacts activities of daily living, employment and overall quality of life.

Research into pressure ulcer etiology has demonstrated that the damaging effects of pressure are related to both its magnitude and duration. Based upon this and related work, clinical interventions have been based upon the premise that both the magnitude and duration of loading are important. All persons with SCI are taught to relieve pressure on their buttocks regularly. While this is prudent training, it is based upon inference rather than direct evidence.

This project is the first to monitor pressure relief maneuvers and weight-shifting activities during the first year after injury. The project has been designed to fill two significant gaps in the current state of knowledge: 1) accurate measurement of dedicated pressure reliefs and other weight shift activities and 2) the relationship between activities that redistribute weight on the buttocks and the occurrence of pressure ulcers.

15. SUBJECT TERMS
Pressure ulcer; spinal cord injury, wheelchair seating

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1. Introduction

Pressure ulcers (PU) are the most costly secondary complication following an SCI. In addition to the medical costs, the development of a pressure ulcer adversely impacts activities of daily living, employment and overall quality of life.

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2. Keywords

Wheelchair, wheelchair cushion, spinal cord injury; pressure ulcer; pressure relief, weight shift; data logger

3. Accomplishments

Major goals of the project and accomplishments under these goals

Task 1. Design, configure and test weight shift sensor and weight shift monitors (months 1-8)

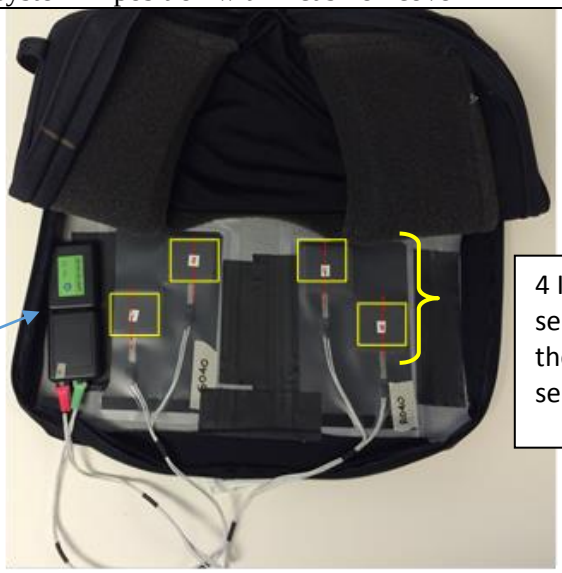
Design of weight-shift monitoring system

The weight-shift monitoring system is comprised of a weight shift sensor and a weight shift monitor. The weight shift sensor is placed underneath the wheelchair cushion to monitor forces on the seat surface. The weight shift monitor is composed of a 4 channel analog voltage input and data logger

After review of design specifications and testing, instrumentation from Gulf Coast Data Concepts (GCDC) was selected for the weight-shift monitor. This US-based company met specifications at a lower cost compared to a European company. Interlink sensors were selected for the weight shift sensor based upon testing and comparison with FlexiForce sensors. GCDC were provided Interlink samples along with response characteristics to facilitate the design, fabrication and testing of the interfacing circuit.

Multiple prototypes were exchanged between study personnel and GCDC; during each iteration, testing was deployed to assess the measurement, analog-to-digital conversion and storage of sensor response to loading. Battery life was also evaluated. Testing included cyclical loading of the system suing a buttock model to simulate weight shift activities. Specifically, a buttock model loaded the sensors for 30 minutes followed by partial unloading for 30 seconds. This partial unloading was designed to mimic a pressure relief performed by a wheelchair user. Therefore, the test was designed to validate the ability of the sensors to detect periodic movement after extended periods of loading. Also, the test characterized sensor creep.

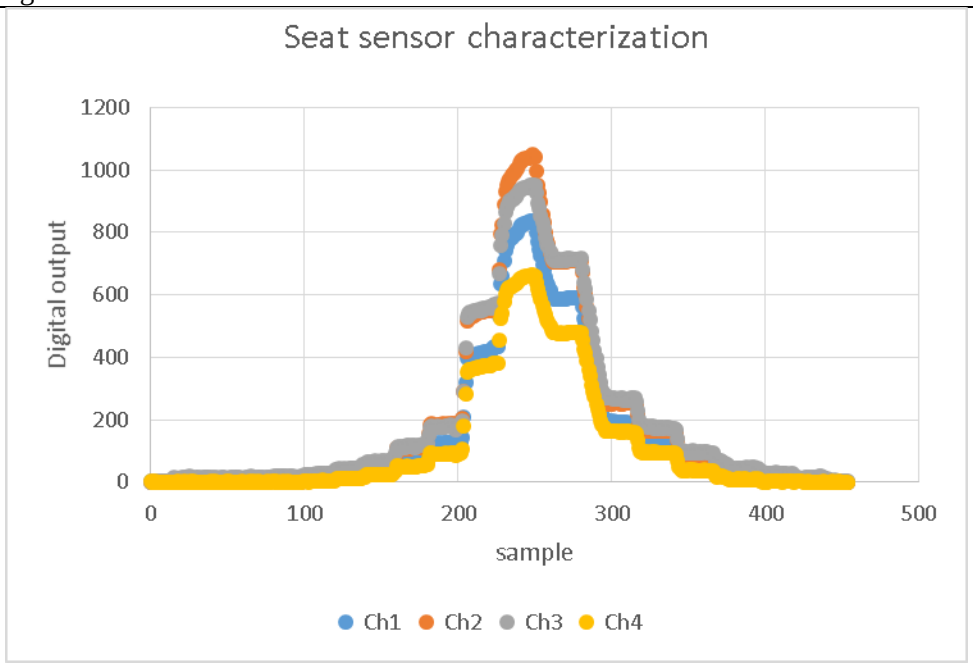
Weight shift monitoring system in position within cushion cover



Fabrication of seat sensors, interfacing with data measurement hardware, and sensor characterization.

Each weight shift sensor is comprised 4 Interlink pressure sensors that must be characterized. A total of 40 complete weight shift sensors were fabricated before characterization. Sensor characterization involved applying known forces in a stepwise manner to document the voltage responses from each individual Interlink sensor. This permitted us to optimize the bridge circuit in the data logger

Characterizing the 4 Interlink sensors within each seat sensor

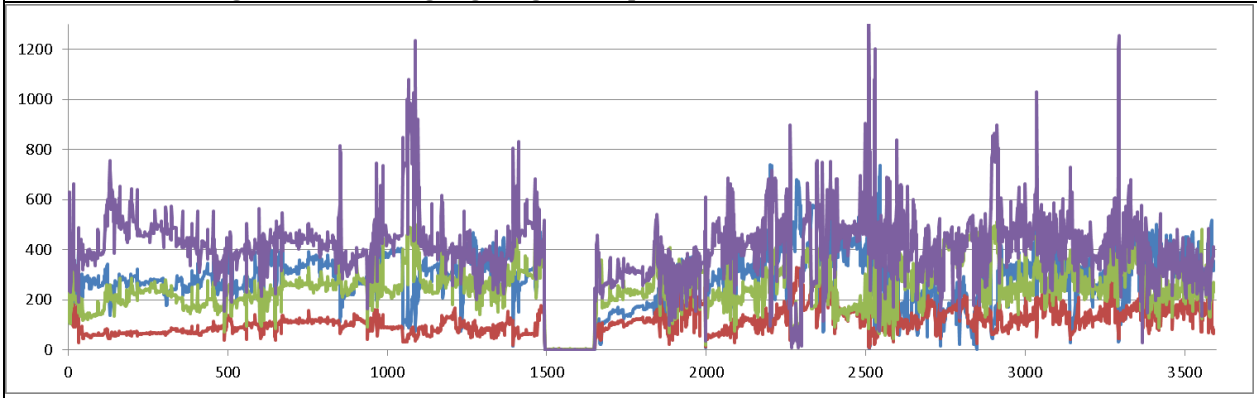


The weight-shift sensor is designed to monitor the loading on a wheelchair cushion. Changes in posture result in changes in load which is measured by the weight shift monitoring system. In order to document the type and

frequency of weight shifting behaviors, force data from the sensors must be categorized. This is a difficult challenge and one that is on-going.

Of note is the fact that the protocol collects a 'training data set' for each subject. This individual assessment is needed because forces on the cushion and changes in force due to movement will differ across people. This training data set because the basis upon which classification is based. The table below depicts 60 minutes of data- one response is from each of the sensors that comprise the weight-shift monitor.

60 minutes of weight shift data- highlighting the responses from each of the 4 sensors



Task 1 has been completed

Task 2. Finalize methodology and submit for IRB approval (months 2-8)
One human subject research protocol is required to complete the Statement of Work. The protocol was developed, submitted and approved at all three sites. The protocol has received HPRO approval

Protocol [HRPO Assigned Number]: SC120127

Title: Pressure relief behaviors and weight shifting activities in persons with SCI

Submitted to and Approved by:

- Georgia Tech, Shepherd Center, Kessler have each approved the protocol
- HRPO

Status:

- Protocol has been approved

Task 2 is complete except for annual continuing reviews performed at all 3 sites and by HPRO

Task 3. Develop research manuals for each facility and train staff (months 6-8)
Research Manual were developed for Kessler and Shepherd Center and were provided to each clinical site after a few rounds of iteration. While the complete Research Manual is extensive, a shorter Reference Manual was also developed for use during subject engagement; this document was included in the YR1 annual report.

Both Shepherd Center and Kessler staff have undergone formal training to establish proper technique and subject protocol.

Task 3 has been completed

Task 4. Enroll and monitor subjects for 12 months (months 9-40)
Subject screening and initial recruitment has ended at Shepherd Center and Kessler. We continue to schedule participants for follow-up visits during their first year post-discharge.

Total patients screened	662
Total Local who met inclusion criteria	119
Total Local who declined	67
Total enrolled	44
Participants returning for follow-up visit	17

Task 5. Synthesize and analyze data (months 41-48)

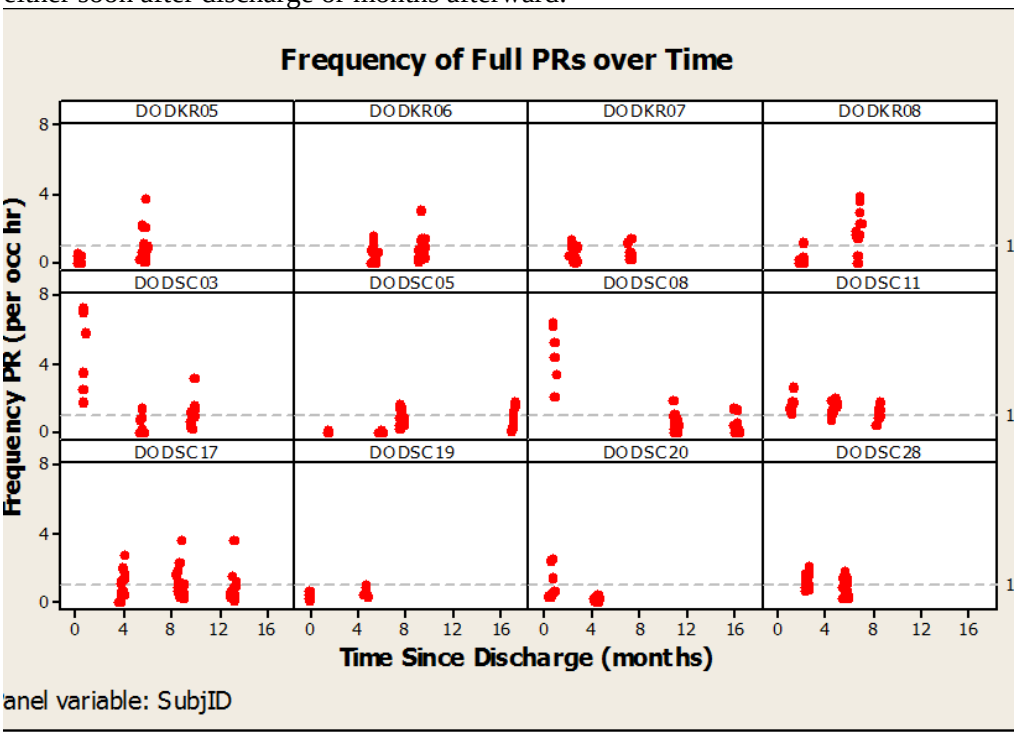
5a. Collect and aggregate data (month 41)

5b. Iteratively run analysis and modeling (month 42-48)

Data synthesis and analysis activities

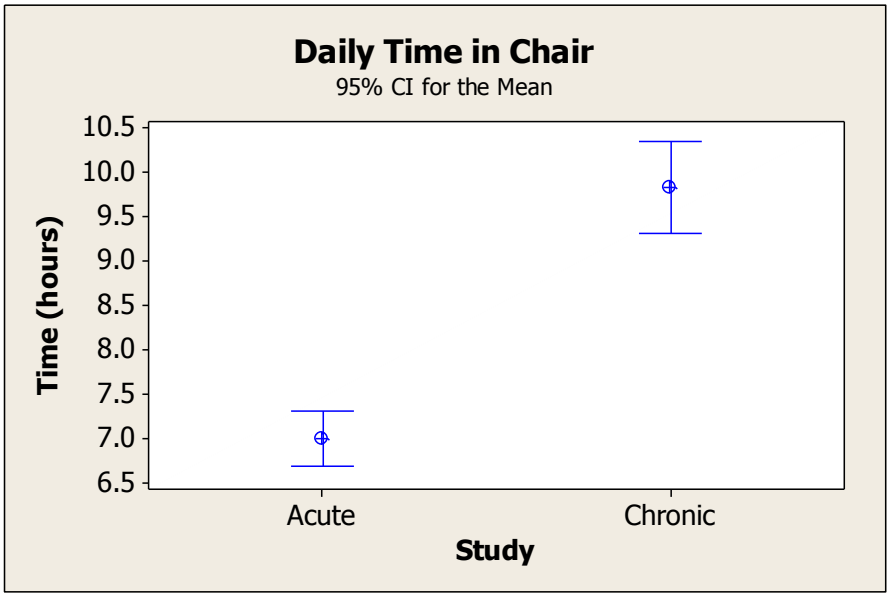
A data processing, review, and documentation pipeline has been established that permits efficient review of the data soon after collection. Processing steps described previously have all been coded in Matlab. Additional checks have been instituted that graph different aspects of the data on its own and relative to other subjects to allow for quick detection of problems in the data set. Final analysis and synthesis will occur after data collection is complete. However, we regularly analyze current data sets as a means to refine analysis and for dissemination purposes. A snapshot of this data follows.

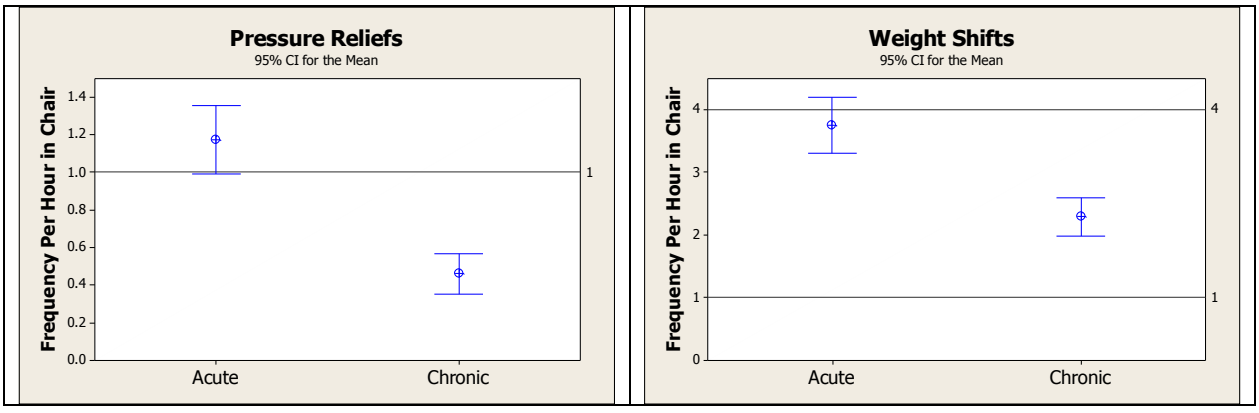
Interesting findings from analysis in this quarter concern assessing Pressure Relief behavior within the first year post-discharge. The figure below depicts the Pressure Relief behavior of 12 persons within their first year post-discharge. One can readily visualize that, as a group, no consistent change in behavior is evident. Some persons appear to decrease their PR frequency while others appear to increase them slightly. The most important result, however, is that all persons perform very few PRs and are not adhering to the regimen taught during rehab- either soon after discharge or months afterward.



Other analysis includes comparing persons with recent SCI to those with longer term injuries. This project studies persons in their first year post injury so comprise the 'recent' cohort. Data previously collected, as a part of another project, recruited persons at least 2 years post-injury and comprise the 'long term' or 'chronic' cohort. This comparison includes 31 persons with 'recent SCI monitored for 359 days and 29 persons with chronic SCI who were monitored for 225 days.

The results show a clear distinction between groups. Persons with chronic SCI sit in their wheelchairs about 2 ½ hours longer in a given day. However, persons with recent SCI perform more pressure reliefs and weight shifts per hour than persons with chronic SCI. This may indicate that the rehabilitation regimen that is taught during rehabilitation has an impact on weight-shifting behavior but that behavior changes over time. One clinical implication is that follow-up education is required or some other intervention is needed to better motivate persons to maintain a weight-shift regimen.





What opportunities for training and professional development has the project provided?

This project has increased our knowledge about in-seat movement of full time wheelchair users. This information has clinical relevance because wheelchair users with spinal cord injury are taught a rehabilitation regimen consisting of regular pressure reliefs and weight shifts.

How were the results disseminated to communities of interest?

We continue to report our data at conferences that target clinicians (physical and occupational therapists and physicians) DME suppliers, and wheelchair users.

Sonenblum SE, Sprigle S. You Got to Move It, Move It! Pressure Reliefs, Weight Shifts, and Wheelchair Mobility in Individuals with SCI. Paper presented at: RESNA2016; Arlington, VA.

Sonenblum SE, Dyson-Hudson T. You Got to Move it, Move it! Paper presented at: 32nd International Seating Symposium2016; Vancouver, BC, Canada.

Sonenblum SE, Sprigle S, Martin JS. Everyday sitting behavior of full time wheelchair users. *J Rehabil Res Dev.* 2016;53(5).

Sonenblum SE. The role of weight shifts in pressure ulcer prevention 2016 ASCIP Educational Conference, Nashville

Sprigle S, Sonenblum SE. *Pressure Injury Prevention. Seated but not still*. Rehab Management: Anthem Systems; 2016.

4. Impact

What was the impact on the development of the principal discipline(s) of the project?

Many disciplines are involved in the rehabilitation of persons with spinal cord injury and the prevention of pressure ulcers, including physical and occupational therapists, rehabilitation physicians and wheelchair suppliers. The results of this study have been included in presentations and publications targeting each of these disciplines. While the impact of new clinical findings is hard to assess at this time, the information collected in this project is novel with respect to the current state of knowledge. As such, a significant potential impact can result.

What was the impact on other disciplines?

Nothing to report

What was the impact on technology transfer?

Intellectual property that resulted, in part, from this project has been identified with a provisional application for patent submitted. This initiated a technology transfer process that includes seeking commercialization partners. We are currently discussing technology transfer with two companies.

What was the impact on society beyond science and technology?

Nothing to report

5. Changes/Problems

Changes in approach and reasons for change

As detailed in prior reports, recruitment is difficult in a study such as this. The actual subject involvement is not rigorous. In fact, the set-up procedure takes less than 60 minutes. The challenge is in gaining interest from persons who are newly injured and have a pending discharge date. We noted this challenge while engaging potential subjects and come to the conclusion that asking someone to commit to a 12 month study before they have even been discharged was overwhelming to them.

We responded to this challenge by better articulating subject involvement. Note- there was no change in the objectives or the targeted data set, rather a change in fully explaining the study to insure autonomy. Specifically, presented this study in sections instead of as a 12 month commitment. Operationally, this targets recruitment for the initial visit within 1 month of discharge and in concert with another outpatient hospital visit. We also express our intent to schedule the participants for additional testing- if he or she is so interested.

An additional change in approach included the recruitment of potential participants within the first year of discharge, but not necessarily within 1 month of discharge. We follow them from enrollment until 12 months post discharge, for however many visits that may include.

Actual or anticipated problems or delays and actions or plans to resolve them

We extended our recruitment period and follow-up period as a means to maximize our subject involvement. This was made possible by an extension of the project period as approved by the project sponsor.

Changes that had a significant impact on expenditures

An extension without funds (EWOF) was requested and approved which extended the project until 2017. This extension does not impact the total budget or expected expenditures.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

None

Significant changes in use or care of human subjects

None

Significant changes in use or care of vertebrate animals.

N/A

Significant changes in use of biohazards and/or select agents

N/A

6. Products

Publications, conference papers, and presentations

Sprigle, S. Dedicated pressure reliefs and functional in-seat movements as pressure redistributing strategies" 2015 Nordic Seating Symposium, Oslo, Norway

Sonenblum, SE "Do you know how people move in their wheelchairs? Measuring and describing real-world wheelchair use." 2015 Annual RESNA Conference, Denver, CO

Sonenblum SE, Sprigle S. You Got to Move It, Move It! Pressure Reliefs, Weight Shifts, and Wheelchair Mobility in Individuals with SCI. Paper presented at: RESNA2016; Arlington, VA.

Sonenblum SE, Dyson-Hudson T. You Got to Move it, Move it! Paper presented at: 32nd International Seating Symposium2016; Vancouver, BC, Canada.

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Sprigle S, Sonenblum SE. *Pressure Injury Prevention. Seated but not still*. Rehab Management: Anthem Systems; 2016.

Website(s) or other Internet site(s)

Nothing to report

Technologies or techniques

The activities of this project has contributed to the development of system capable of measuring in-seat movement of wheelchair users. The system is comprised of a hardware system and algorithms capable of classifying both pressure reliefs and weight shifting activities. This system was submitted to Georgia Tech for assessment of intellectual property. Georgia Tech elected to file a provisional application following their intellectual property procedures.

Inventions, patent applications, and/or licenses

US Provisional Patent Application
A Wheelchair In-Seat Activity Tracker
Application No.: 62/372,33
Filed: 9 August 2016

Other Products

Nothing to report

7. Participants & Other Collaborating Organizations

Name:	Stephen Sprigle
Project Role:	Principal Investigator – GIT
Researcher Identifier (ORCID ID):	0000-0003-0462-0138
Nearest person month worked:	1
Contribution to Project:	designed sensor testing protocol, reviewed sensor testing data; processed subagreements with Shepherd Center and Kessler; worked on IRB submission; subject set-up
Funding Support:	State of Georgia

Name:	Sharon Sonenblum
Project Role:	Lead Investigator- GIT
Researcher Identifier :	
Nearest person month worked:	3
Contribution to Project:	established sensor and logger design specs; engaged data logging manufacturer; worked on classification algorithm; reviewed sensor testing data; submitted IRB application to GIT and Shepherd IRB ; Committees; subject set-up
Funding Support:	NIDRR (Dept of Education)

Name:	Trevor Dyson-Hudson, M.D.
Project Role:	Kessler PI
Researcher Identifier	
Nearest person month worked:	1
Contribution to Project:	Dr. Dyson-Hudson serves as site-PI at our collaborative clinical site, Kessler Foundation and Kessler Institute.
Funding Support:	NA

Name:	Marina Moldavsky
Project Role:	Shepherd study Coordinator
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1
Contribution to Project:	Screen and enroll participants. Assist with carrying out protocol during each visit. Schedule participant visits. Input data and maintain all participant logs.
Funding Support:	

Changes in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to report

What other organizations were involved as partners?

Nothing to report

8. Special Reporting Requirements

9. APPENDICES:

Development of Pressure Relief Monitor data-processing algorithm

The sensor mat consists of 4 force sensors configured in a trapezoidal shape (Figure 2). The mat is placed *underneath* the wheelchair cushion so that its presence does not affect cushion performance. If placed on top of the cushion, it would alter the surface upon which the buttocks are positioned and impact cushion performance. Underneath the cushion, the measured forces are not as easily interpretable because the cushion redistributes loading between the buttocks and the mat. Therefore, extensive work has focused on algorithm development to accurately classify different weight shifting maneuvers.

The four force sensors were used to define four features of the loading profile: center of pressure (CoP) in the medial-lateral direction, CoP in the fore-aft direction, and the maximum force on the right and left sides. Each of these features were evaluated with respect to a continually defined baseline force profile which follows the users' typical seated posture during quiet sitting throughout the day. The four features relative to the baseline were used in a classification algorithm to determine overall weight shift status.

To develop the classification algorithms, training data was taken using the weight shift sensor (beneath the cushion) in combination with an interface pressure mat resting on top of the cushion. In the training set data, all weight shift sensor features were classified as either a weight shift or upright sitting according to the associated normalized interface pressure values. This represents the "ground truth." Weight shift sensor features from the daily data were then classified by identifying the Euclidean nearest neighbors in the training set's features and the associated ground truth status of upright sitting or weight shift.

The algorithm was designed to categorize force responses from the sensor into 3 groups:

- *Weight Shift (WS)* – either side is partially unloaded (<70% upright loading) for > 15 seconds
- *Pressure Relief (PR)* – left and right sides fully unloaded for > 15 seconds and < 2 minutes
- *Out of Chair* – fully unloaded for > 2 minutes

As indicated by the definitions, weight shifts and pressure reliefs were distinguished by the magnitude and duration of off-loading. Our previous study into weight shifts using forward and side leans informed these definitions.[1]. This study found that weight-shifts involving partial off-loading for relatively short periods of time significantly reduced interface pressures and increased blood flow. This level of off-loading is achieved by postural changes during sustained reaching, leaning and other functional activities that shift the center of mass of the wheelchair user. In distinction, pressure reliefs fully off-load the load-bearing portions of the buttocks and tend to involve more volitional movements for that purpose. Occupancy of the wheelchair was also tracked since the frequencies of weight shifting activities are based upon occupancy-hours. Validation of the classification algorithm found that both the sensitivity and specificity exceeded 83%.

[1] S. Soneblum, T. Vonk, T. Janssen, and S. Sprigle, "Effects of wheelchair cushions and pressure relief maneuvers on ischial interface pressure and blood flow in people with spinal cord injury", Archives of Physical Medicine and Rehabilitation, Vol. 95 no.7, pp. 1350-1357, July 2014.